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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,705	07/12/2001	Daniel P. Bednarik	PF138P1C1	8314

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HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

3-1

Office Action Summary	Application No.	Applicant(s)	
	09/902,705	BEDNARIK ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) *11,21,32,48,58,69,75 and 76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,10,12-20,22-31,33-47,49-57,59-68 and 70-74* is/are rejected.

7)☒ Claim(s) *7 and 8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/17/03
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

Claims 1-76 are pending.

It is noted that the examination of the instant application has been assigned to a different Examiner in Group Art Unit 1652.

Applicant's election with traverse of Group I, claims 1-10, 12-20, 22-31, 33-47, 49-57, 59-68, 70-74 drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 2, vectors, host cells, and a method to produce the polypeptide, in a communication filed on 9/17/2003 is acknowledged.

Applicant's traverse is on the ground(s) that 37 CFR 1.141 indicates that if claims to product, process of making and process of use are included in an application, a three way requirement for restriction can only be made where the process of making is distinct from the product. Applicants submit that it is unlikely that one of skill in the art would chemically synthesize a recombinant vector, therefore the process of making the vector and the product, i.e. vector, should be examined together. In addition, Applicants request that if any of the claims in Group I is found allowable, then the claims in Groups II and III should be rejoined and examined for patentability.

Applicant's arguments have been fully considered but are not deemed persuasive to withdraw the restriction requirement. While it is agreed that the it is not common to chemically synthesize an entire vector, as indicated by the previous Examiner of record, a polynucleotide can be made by chemical synthesis. As such, the product, i.e. vector, can be made by a materially different method from that in Group II. In regard to the rejoinder of Groups II-III, drawn to a method of making the vector in Group I and a method of use of the polynucleotide in Group I, respectively, it is noted that methods of making and using the product will be examined according to *In re Ochiai, In re Brouwer* and 35 USC § 103 (b) once the product is found allowable. Withdrawn process claims that are not commensurate in scope with

an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

The requirement is deemed proper and therefore is made FINAL.

Claims 21, 32, 48, 58, 69, 75-76 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

1. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 08/461,031 filed on 06/05/1995 and PCT/US94/11914 filed on 10/19/1994.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 9/17/2003 is acknowledged. The references listed in the information disclosure statement filed on 9/17/2003 as AK and AL are not in conformance with MPEP § 609 and has not been considered for the following reasons. No publication date has been indicated for the instant reference. The remainder of the references in the submission is in compliance with the provisions of 37 CFR 1.97 and have been considered by the Examiner.

Specification

3. The disclosure is objected to for the following reasons. According to paragraph 18 of the specification, the bottom line in the alignment shown in Figure 2 corresponds to SEQ ID NO: 2. Figure 2 shows a polypeptide consisting of 218 amino acids. It is noted, however, that the polypeptide of SEQ ID NO: 2 as disclosed in the sequence listing contains 212 amino acids. As such, the bottom line in the alignment shown in Figure 2 is not that of SEQ ID NO: 2. Appropriate correction is required. Applicants should be careful not to introduce new matter in future amendments to the specification.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 27, 29-31, 33-36, 64, 66-68, 70-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 27 , 29, 64 and 66 (claims 30-31, 33-36, 67-68, 70-73 dependent thereon) are indefinite in the recitation of "complementary strand" for the following reasons. The term "complementary" renders the claim indefinite because it is unclear which "complements" are encompassed by the claims. Fragments of any size which are complementary to the polynucleotides claimed can be considered as "complements". Applicants have not define the term "complementary", as it relates to size, in the specification either. If applicants wish to claim the entire complementary strand, it is suggested that the term "complementary" be replaced with "completely complementary" or similar. For examination purposes, it will be assumed that the term "complementary strand" refers to "the complete complement". Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-6, 9-10, 12-20, 22-31, 33-43, 46-47, 49-57, 59-68, 70-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-6, 9-10, 17-20, 27-31, 38-43, 46-47, 54-57, 64-68 are directed to genera of polynucleotides of any function (1) comprising a nucleotide sequence encoding a polypeptide having at least 90% or 95% sequence identity to the polypeptide of SEQ ID NO: 2 (or polypeptide encoded by the cDNA of ATCC deposit No, 75844) or any fragment of the polypeptide of SEQ ID NO: 2 (or polypeptide encoded by the cDNA of ATCC deposit No, 75844) with HPRT activity, (2) comprising a nucleotide sequence encoding at least 30 or 50 contiguous amino acids of the polypeptide of SEQ ID NO: 2 (or the polypeptide encoded by the cDNA of ATCC deposit No, 75844), or (3) comprising at least 50 contiguous nucleotides of nucleotides 626-1260 of SEQ ID NO: 1 or the coding sequence in the cDNA of ATCC deposit No. 75844. Claims 12-16, 22-26, 33-37, 49-53, 59-63, 70-74 are directed to vectors comprising the polynucleotides of (1)-(3), host cells comprising the polynucleotides of (1)-(3), and methods of recombinantly producing the polypeptides encoded by the polynucleotides of (1)-(3).

The specification discloses the structure and function of the polypeptide of SEQ ID NO: 2 as well as that of the corresponding polynucleotide, i.e. SEQ ID NO: 1. However, the specification does not contain any disclosure of the structure or function of all the nucleic acids included in the claimed genera. The genus of nucleic acids claimed is a large variable genus with the potentiality of encoding many different proteins. As taught by the art, a high degree of structural homology may not result in functional homology. Witkowski et al. (Biochemistry 38:11643-11650, 1999) teaches that one amino acid substitution transforms a β-ketoacyl synthase into a malonyl decarboxylase and completely eliminates β-ketoacyl synthase activity. Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* were found to be hydroxylases once tested for activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity

catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al. (Science 282:1315-1317, 1998) teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase. Therefore, the claimed genera of polynucleotides have the potentiality of encoding proteins of many different functions.

In addition, while a sufficient written description of a genus of DNAs may be achieved by a recitation of a representative number of DNAs defined by nucleotide sequence or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus, in the instant case, the recited structural features, such as "30 contiguous amino acids of the polypeptide of SEQ ID NO: 2", "50 contiguous amino acids of the polypeptide of SEQ ID NO: 2", "50 contiguous nucleotides of nucleotides 626-1260 of SEQ ID NO: 1", do not constitute a substantial portion of the genus as the remainder of any nucleic acid comprising said structural elements is completely undefined and the specification does not define the remaining structural features for members of the genus to be selected. Many functionally and structurally unrelated polynucleotides are encompassed by these claims. The specification only discloses a single species of the claimed genera which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the claimed genera. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

9. Claims 38-47, 49-57, 59-68, 70-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel vectors. Since the vectors are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The specification does not disclose a repeatable process to obtain the vector and it is not apparent if the DNA sequences required are readily available to the public. Accordingly, it is deemed that a deposit of these vectors should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that Applicants have made a biological deposit as indicated in page 4, paragraph 22, and have indicated that such deposit was made under the terms of the Budapest Treaty and will be made available to a patent office signatory to the Budapest Treaty. This statement however is not deemed sufficient to meet the requirements in regard to public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain/vector has been deposited under the Budapest Treaty and that the strain/vector will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.1809, Applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

a. during pendency of this application, access to the invention will be afforded to the Commissioner upon request;

b. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

c. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

d. the deposit will be placed if it should ever become unviable.

10. Claims 1-6, 9-10, 12-20, 22-31, 33-43, 46-47, 49-57, 59-68, 70-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding the polypeptide of SEQ ID NO: 2 or the cDNA contained in ATCC deposit No. 75844, does not reasonably provide enablement for a polynucleotide of any function (1) comprising a nucleotide sequence encoding a polypeptide having at least 90% or 95% sequence identity to the polypeptide of SEQ ID NO: 2 (or polypeptide encoded by the cDNA of ATCC deposit No, 75844) or any fragment of the polypeptide of SEQ ID NO: 2 (or polypeptide encoded by the cDNA of ATCC deposit No, 75844) with HPRT activity, (2) comprising a nucleotide sequence encoding at least 30 or 50 contiguous amino acids of the polypeptide of SEQ ID NO: 2 (or the polypeptide encoded by the cDNA of ATCC deposit No, 75844), (3) comprising at least 50 contiguous nucleotides of nucleotides 626-1260 of SEQ ID NO: 1 or the coding sequence in the cDNA of ATCC deposit No. 75844, (4) vectors comprising (1)-(3), (5) host cells comprising (4), or (6) methods of producing the polypeptides encoded by (1)-(3). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breath of the claims.

The scope of the claims as described above is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides of unknown function encompassed by the claims. As indicated above, the specification discloses the function and structure of

the polypeptide of SEQ ID NO: 2 and the corresponding polynucleotide, i.e. SEQ ID NO: 1, however it does not provide any information as to the structures or functions of all the polynucleotides encompassed by the claims. Furthermore, the specification does not provide any information as to the critical structural elements required in any polynucleotide to encode a hypoxanthine phosphoribosyl transferase (HPRT) nor does it provide any information as to (1) which 30 or 50 amino acids of the polypeptide of SEQ ID NO: 2 or which 50 contiguous nucleotides of nucleotides 626-1260 of SEQ ID NO: 1 are essential for the only function disclosed, i.e. HPRT, or (2) which amino acids in the polypeptide of SEQ ID NO: 2 can be modified (i.e. substituted, inserted or deleted) to create a structural homolog as recited in the claims with HPRT activity.

The state of the art teaches the unpredictability of determining function using structural homology and discloses examples of how small structural changes can lead to major changes in function. See the teachings of Broun et al., Van de Loo et al., Seffernick et al., and Witkowski et al. already discussed. Since structure determines function, one of skill in the art would require some knowledge or guidance as to how structure correlates with the desired function. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to maintain the desired function, and the unpredictability of the prior art in regard to function based on homology, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to (1) screen and isolate those polynucleotides, as encompassed by the claim, which encode proteins of similar function to that disclosed for the polypeptide of SEQ ID NO: 2, or (2) determine the actual function of the claimed polynucleotides. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-10, 12-20, 22-31, 33-47, 49-57, 59-68, 70-74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 09/189833. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-10, 17-20, 27-31, 38-47, 54-57, 64-68 are directed to polynucleotides (1) comprising a nucleotide sequence encoding a polypeptide having at least 90% or 95% sequence identity to the polypeptide of SEQ ID NO: 2 (or polypeptide encoded by the cDNA of ATCC deposit No, 75844) or any fragment of the polypeptide of SEQ ID NO: 2 (or polypeptide encoded by the cDNA of ATCC deposit No, 75844) with HPRT activity, (2) comprising a nucleotide sequence encoding at least 30 or 50 contiguous amino acids of the polypeptide of SEQ ID NO: 2 (or the polypeptide encoded by the cDNA of ATCC deposit No. 75844), (3) comprising at least 50 contiguous nucleotides of nucleotides 626-1260

of SEQ ID NO: 1 or the coding sequence in the cDNA of ATCC deposit No. 75844, (4) comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO: 2 (or the polypeptide encoded by the cDNA of ATCC deposit No. 75844), and (5) encoding a polypeptide comprising a fragment of the polypeptide of SEQ ID NO: 2 (or the polypeptide encoded by the cDNA of ATCC deposit No. 75844). Claims 12-16, 22-26, 33-37, 49-53, 59-63, 70-74 are directed to vectors comprising the polynucleotides of (1)-(5), host cells comprising the polynucleotides of (1)-(5), and methods of recombinantly producing the polypeptides encoded by the polynucleotides of (1)-(5).

Claims 1-9 of copending Application No. 09/189833 are directed in part to (1) a polynucleotide encoding a polypeptide 100% identical to that of SEQ ID NO: 2, (2) a polynucleotide 100% sequence identical to that of SEQ ID NO: 1, (3) the cDNA contained in ATCC deposit No. 75844, (4) a polynucleotide comprising nucleotides 626-1263 of SEQ ID NO: 1, (5) vectors comprising said polynucleotides, (6) host cells transformed with the vector of (5), and (7) a method to produce the polypeptide encoded by the polynucleotides of (1)-(4). Therefore, claims 1-9 of copending Application No. 09/189833 anticipate claims 1-10, 17-20, 27-31, 38-47, 54-57, 64-68 of the instant application as written.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claim is in condition for allowance.

14. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
November 13, 2003

REBECCA E. PROUTY
PRIMARY EXAMINER
1600